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EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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02/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,334	Applicant(s) HAMMOCK ET AL.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70 and 118-132 is/are pending in the application.
- 4a) Of the above claim(s) 118,123,124 and 130 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70,119-122,125-129,131 and 132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed November 26, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed in original or modified form below is herein withdrawn. Applicant has cancelled all pending claims except claim 70 and entered new claims 118-132, thus the previous rejections are withdrawn as moot.

The Declaration filed on July 9, 2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the MORISSEAU reference. Specifically, as admitted by Applicant in the Remarks (page 32 of 39), the declaration lacks Dr. Newman's signature. Thus the new rejections set forth below are not overcome by the declaration.

Election/Restrictions

Applicant's amendments are ineffective in preventing/obviating certain rejections readable upon the newly presented claims. Applicant is reminded that in Markush practice the examiner is not required to extend the search unnecessarily to non-elected species when art is still applicable. New claims 118, 123, 124 and 130 do not read upon the previously elected and/or identified species, and therefore are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 16, 2006.

Information Disclosure Statement

While the examiner appreciates Applicant's submission of the references not previously considered, the references were not cited on a new PTO-1449, and thus the information disclosure statement filed November 26, 2007 fails to comply with 37 CFR 1.98(a)(1), which

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requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 70, 120, 121 and 129 are objected to because of the following informalities:

Claims 70, 120 and 121 depend from currently withdrawn claim 118.

Claim 129 uses commas between the species, however page 19 of 39 of the amendment the species are no longer separated by commas. Further, 'and' is required between the last two species of the Markush group.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 131 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 131 recites “the subscript m is 1”, however the examiner does not find the variable ‘m’ in the compound, or a variable of a subunit, and thus it is unclear as to what the variable belongs, and renders the claim confusing as to whether the compound claimed is incomplete in the description or formula.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

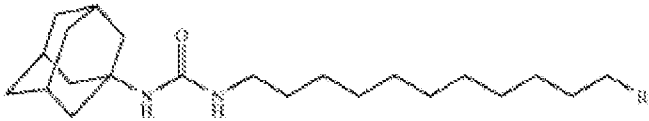
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 129, 131 and 132 are rejected under 35 U.S.C. 102(a) as being anticipated by MORISSEAU (C. Morisseau et al. Biochem. Pharm. (2002) 63, page 1599-1608).

As discussed above, Applicant’s declaration under 37 CFR § 1.131 is ineffective, and thus the Morisseau is properly relied upon in a rejection.

The instant claims are drawn generally to inhibitors of soluble epoxide hydrolases,

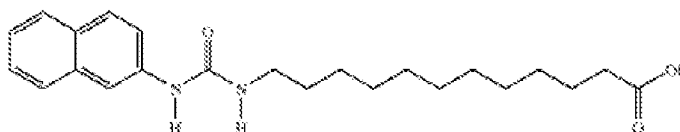
including the elected species , where R is

COOH, and pharmaceutical compositions thereof. Morisseau teaches the species as compound 43 (Table 5, page 1605).

Claims 70, 119-122 and 125-128 are rejected under 35 U.S.C. 102(a) as being anticipated by KROETZ (US Patent 6,531,506 B1).

While Applicant's amendments to the claims no longer allowed compounds 297 and 125 to read on the claims, Applicant's amendments fail to overcome other compounds within the teachings of Kroetz.

Kroetz teaches compound 283:



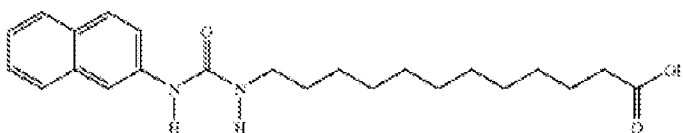
(Table 1, column 33/34). Kroetz teaches pharmaceutical of the compounds are formulated with carriers or excipients and provides various examples of such formulations (column 43, line 36- column 45, line 10). The compound is $R^1 = \text{Naphthyl aryl}$; P^1 is NHC(O)NH ; L^1/L^2 combined form the alkyl chain ($n=11$), $P^3 = \text{C(O)OH}$, $n=0$, $m=1$.

Claims 70, 119-122 and 125-128 are rejected under 35 U.S.C. 102(e) as being anticipated by KROETZ(I) (US 2004/0092487 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

While Applicant's amendments to the claims no longer allowed compounds 297 and 125 to read on the claims, as above, Applicant's amendments fail to overcome other compounds within the teachings of Kroetz(I).

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Kroetz(I) teaches compound 283:

(Table

1, page 17). The compound is $R^1 = \text{Naphthyl aryl}$; P^1 is NHC(O)NH ; L^1/L^2 combined form the alkyl chain ($n=11$), $P^3 = \text{C(O)OH}$, $n=0$, $m=1$. Kroetz(I) teaches pharmaceutical of the compounds are formulated with carriers or excipients and provides various examples of such formulations (page 23, ¶ 0056 to ¶ 0066).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 129, 131 and 132 are ejected under 35 U.S.C. 103(a) as being unpatentable over RICHTER in view of Brocchini, as applied to claims 58, 59, 70, 105-109 and 111-114, *supra*, in further view of ABDULLA (US Patent 4,252,954).

Applicant argues that the compounds are not obvious asserting that there is no motivation to modify the compounds of Richter (Remarks, page 36 of 39) and alleges that the examiner relies upon hindsight reconstruction to arrive at the conclusion of obviousness (Remarks, page 38 of 39). Applicant further asserts that, “In the absence of an actual suggestion to combine the

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elements to achieve the results of the present invention, is not sufficient to support a *prima facie* case of obviousness.” (emphasis added, Remarks, page 38 of 39).

Respectfully, the examiner disagrees with Applicant's arguments. As set forth previously, the MPEP sets forth that similar properties may be presumed when the compounds are similar in structure. Further, by Applicant's own admission, the compounds of Richter have not been compared to the instantly claimed compounds (Remarks, spanning pages 37 and 38), thus it is only Applicant's opinion that the compounds are different. It is noted that MPEP § 2145 states, “The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness.”).

Additionally, it is noted that the sEH activity upon which applicant relies (e.g. Remarks, page 38 of 39) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is also reminded that MPEP 2141 provides that a compound may be obvious even if the prior art compound does not share the same utility (“See e.g., *In re Dillon*, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (en banc) (“[I]t is not necessary in order to establish a *prima facie* case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the

prior art that the claimed compound or composition will have the same or a similar utility **as one newly discovered by applicant**”- MPEP 2141).

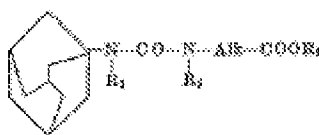
Furthermore, it should be noted that KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness (*See Ex Parte Smith*, USPQ2d, slip op. 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR v. Teleflex*, 82 USPQ2d 1396). Additionally, it appears as if Applicant is improperly requiring the examiner to provide an anticipatory reference in order to render obvious the claimed compounds.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, the compounds of Richter are taught at several lengths, all sharing similar properties. Thus, given that compounds having similar structures are expected to have similar properties, one would have modified the compounds to varying the carbon chain lengths with the expectation that they would function similarly. Obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties. See, e.g., *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Richter teaches antiviral compounds N(1-adamantyl)-N'-[10-carboxydecyl(-1)]urea (Example II, column 5), and the esters N(1-adamantyl)-N'-[10-carbethoxydecyl(-1)]urea

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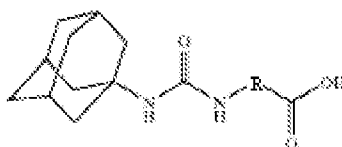
(example XIX, column 9) and Ad-NH-C(O)-NH-(CH₂)₃C(O)O-Et (Table, column 4). It is noted that the esters, e.g. Ad-NH-C(O)-NH-(CH₂)₃C(O)O-Et, can read upon the claims as Ad is R¹, urea is P¹, L¹ is propyl (or decyl), P² is C(O)O and L² is ethyl. Richer further teaches the



compounds are of the generic formula , where R_{1 and 2} are H or alkyl and R₃ is H or an ester (Abstract) and where Alk is 1 to 10 carbons.

Richter additionally teaches that the antivirals may be used alone or in combination with other therapeutically active agents and, accordingly, they are valuable adjuncts in the antiviral field.” (column 1, lines 42-45).

The difference between the instant claims and the teachings of Richter, is that while



Richter teaches the compounds with R generically being an alkyl chain (abstract) and more specifically being an alkyl chain of 1-10 (R=1 to 10 carbons), and embodiments therein, Richter does not teach R=11 or 12 carbon species.

It would have been obvious to have made any R=alkyl species, including the R=11 or 12 carbon species, in order to make an antiviral adamantly urea derivative, as Richter teaches that any alkyl group may be placed as R.

One would have been motivated to have made the compounds, including the R=11 or 12 species, as Richter teaches broadly that R can be any alkyl (abstract), and provides more specifically R is 1-10 carbon atoms and provides examples therein, e.g. R=10 carbon.

Further, the MPEP states that, “In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. *See also In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) (“When chemical compounds have very close’ structural similarities and similar utilities, without more a *prima facie* case may be made.”)” (MPEP § 2144.08). Here, because the instantly claimed compounds are so close in structure to the antivirals disclosed by Richter, differing by one or two carbon in the claimed compound, and are embraced by the genus of Richter, the instantly claimed compounds would be expected to have similar properties with the compounds of Richter, and thus one would have been motivated to have made the compound with R=11 or 12 carbons.

One would have had a reasonable expectation for success in making the antiviral adamantly urea compounds, including the R=11 or 12 carbon, with antiviral activity, as Richter teaches that any adamantyl urea embraced by the genus would have antiviral activity, and provides examples therein, and Abdulla teaches various adamantyl compounds are known as antivirals, where it is shown that the adamantyl group confers the antiviral activity.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole

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was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant requests that the Provisional Obviousness-Type double patenting rejections be held in abeyance until all claims are otherwise allowable. Respectfully, there is no such provision in the MPEP for such requests. The rejections are set forth below.

With regards to

Claims 70, 119-122, 125-129, 131 and 132 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 and 28-60 of copending Application No. 11/256,685 (claims of 3/3/06). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are drawn to overlapping generic claims of compounds and pharmaceutical

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compositions, wherein 11/256,685 additionally provides for a method of using the compounds. In looking to the specification for the compounds that provide support for the claims, compound 687 is found in Table 17. Additionally, other species within Application 11/256,685 which also provide support for the claims are found within the tables and claimed, e.g. claim 28 identifies the compounds of Table 18.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

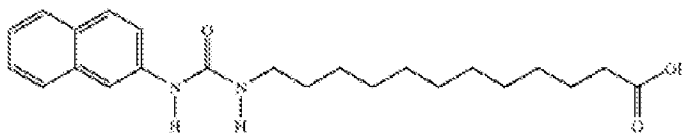
Claims 70, 119-122, 125-129, 131 and 132 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 46 of copending Application No. 10/694,641 (claim set of 10/29/07). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 10/694,641 are drawn to methods of using compounds/pharmaceutical compositions which overlap with the instantly claimed compounds, and in practicing the methods, one would necessarily be in possession of the compounds and pharmaceuticals. In looking to the specification to determine which compounds embraced by the genus are capable of being used in the methods, such as the compounds of Table 1, e.g. 297, 425, 276, 515, 381, 157, 143, 181, 168 and 283, which anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 70, 119-122 and 125-128 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,531,506 B1. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the claims of 6,531,506 B1 are drawn to methods of using compounds which overlap in scope with the instantly claimed products, and in practicing the method, one would necessarily be in possession of the compound and pharmaceutical composition. In looking to the specification of 6,531,506 B1 for the compounds that provide support for the

claims, one finds compound 283:



Claims 58, 59, 70, 105-109, 111-114 and 116 are directed to an invention not patentably distinct from claims 1-24 and 28-60 of commonly assigned copending Application No. 11/256,685 for the reasons set forth above.

Claims 58, 59, 70, 105-109 and 111-114 are directed to an invention not patentably distinct from claims 1-11 of commonly assigned U.S. Patent No. 6,531,506 B1 and/or claims 14-18, 21-23, 26-34 and 37-45 of commonly assigned copending Application No. 10/694,641 for the reasons set forth above.

Applicant is again reminded that the examiner has identified two copending Applications and one issued Patent which have been relied upon in rejections under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Conclusion

This application contains claims 118, 123, 124 and 130 drawn to an invention nonelected without traverse in the reply filed on October 16, 2006. A complete reply to the final rejection

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must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654